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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,347	09/25/2001	J. Fernando Bazan	DX0903K1	9754

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DNAX RESEARCH INC.
LEGAL DEPARTMENT
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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/963,347	BAZAN ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/30/6*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2006 has been entered.

Response to Amendment

2. Claim 21 has been cancelled and claim 33 has been amended as requested in the amendment submitted on October 30, 2006. Following the amendment, claim 33 is pending in the instant application. Claim 33 is under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on October 30, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

6. Claim 33 stands rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al. (US Patent 6, 555, 520, April 29, 2003, filed May 9, 2001) for those reasons of record in appropriate sections of previous communications of record.

Briefly, claim 33 is directed to an isolated polypeptide encoded by a nucleic acid of SEQ ID NO: 1 ("IL-B50" polypeptides). Sims et al. document discloses polynucleotide sequences that have 100% identity to the instant SEQ ID NO: 1, thus fully anticipating the instant claim 33. Because the specific, substantial and credible utility of the instant IL-B50 polypeptides, which support the enablement, the disclosure how to use the invention, is only disclosed in the instant application, the effective filing date for the instant invention is determined as the filing date of the instant application (09/25/2001), which makes patent of Sims et al. a proper 102(e) reference.

Applicant traverses the rejection on the premises that "a *prima facie* case of lack of utility has not been established", and that utility of the claimed invention is disclosed in the '318 application (provisional application 60/101,318), p.3 of the Response. Applicant further submits that "the '318 application discloses that IL-B50 is likely to have stimulatory or inhibitory effect on hematopoietic cells", that "IL-B50 may also be useful in the treatment of immune disorders because of its structural similarity to the known cytokine, IL-7" (middle at p.4 of the Response). Applicant states that "[a]bsent the establishment of a *prima facie* case of lack of utility, the allegation that the claimed invention is not entitled to priority in the '318 application is improper" (p. 6 of the Response). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

The instant application is a continuation-in-part of the previously filed application US serial number 09/399,492 ('492 application). The instant claimed invention was previously examined and rejected in the parent '492 application for lack of specific and substantial credible utility under 35 U.S.C. 101 and lack of enablement under 35 U.S.C. 112, first paragraph. Below is a copy of the rejections presented in the '492 application.

7. Claims 1-7 and 9-10 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated polynucleotide encoding a polypeptide and the polypeptide encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant application that the polypeptide described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an

invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to a DNA and the protein encoded thereby of as yet undetermined function or biological significance. It is clear from the instant application that the protein described thereby is similar to Interleukin-7: "The present invention is based, in part, upon the discovery of a new cytokine sequence exhibiting significant sequence and structural similarity to IL-7" (page 4, lines 20-22 of the specification). It has been suggested that "The full length cytokines, and fragments, or antagonists will be useful in physiological modulation of cells expressing a receptor. It is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells, including, e.g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc." (page 9, lines 7-13) (emphasis added by the Examiner).

In the absence of knowledge of the biological significance of this specific DNA and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. First, the similarity of the disclosed DNA to a DNA associated with IL-7, a member of a family of interleukins, which is characterized by a wide and diverse range of activities (see page 2, lines 20-21 - of the specification), does not make the instant DNA or

encoded protein obviously useful. Second, the specification alleges that the sequence similarity of IL-B50 to IL-7 is significant. However, according to the information on sequence alignments (see a copy of the printout provided), the sequence similarity between IL-B50 and IL-7 is only 28.1%. Based on this limited degree of similarity, one of ordinary skill in the art would not reasonably conclude that the disclosed protein possesses any or all of the biological activities of IL-7, especially in light of the specification's statement of "stimulatory or inhibitory effects" (see page 9).

To employ the DNA and the protein in the future methods of modulating physiology or development of a cell is not a real world because it would eventually relate to a protein for which little biological function is known. As it is indicated in the specification of the instant application, it is not clear and can be only assumed at this time that IL-B50 will have an effect, either stimulatory or inhibitory on hematopoietic cells (see page 9 of the specification and earlier in this office action). In other words, to employ a DNA of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claims 1-7 and 9-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Thus, because '492 application did not disclose how to use the instant claimed invention, the priority of the filing date of that application as well as to both provisional applications (60/131,298 and 60/101,318) was denied, see MPEP 201.11 (U.S.C. 120 states that the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112).

9. The instant application presented disclosure of new data obtained after the filing of the previous applications (see pp.64-69), which constitutes a CIP status of the instant application. With respect to the priority date, MPEP 706.02(a) makes it clear that

"(B) If the application is a continuation-in-part of an earlier U.S. application or international application, any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application.

As such, because the instant invention is only fully enabled in the instant specification, the effective filing date of the instant invention is awarded as the filing date of the instant application, 09/25/2001, which makes Sims et al. document a proper prior art under 102(e).

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

December 12, 2006